January 31, 2005

MEMORANDUM

SUBJECT: CASAC Review of Second Draft Particulate Matter Staff Paper

FROM: Karen M. Martin, Group Leader
Health and Ecosystems Effects Group
Office of Air Quality Planning and Standards

TO: Fred Butterfield
Designated Federal Officer
Clean Air Scientific Advisory Committee
EPA Science Advisory Board Staff Office (1400F)

Attached are materials prepared by the Environmental Protection Agency's (EPA) Office of Air Quality Planning and Standards (OAQPS) staff as part of EPA's ongoing review of the national ambient air quality standards (NAAQS) for particulate matter (PM). These materials will be the focus of a review by the Clean Air Scientific Advisory Committee (CASAC) PM NAAQS Review Panel (the CASAC PM Panel), tentatively scheduled for a public meeting to be held in Research Triangle Park, NC, on April 6 - 7, 2005. These materials include the second draft of the PM Staff Paper, *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information*, and other documents as identified below. I am requesting that you forward these materials to the CASAC PM Panel to prepare for that review.

The purpose of the PM Staff Paper is to evaluate the policy implications of the key scientific and technical information contained in EPA's Air Quality Criteria Document (AQCD) for PM (October 2004), and to identify critical elements that EPA staff believes should be considered in the review of the PM NAAQS. The PM Staff Paper is intended to "bridge the gap" between the scientific review contained in the PM AQCD and the public health and welfare policy judgments required of the Administrator in reviewing the PM NAAQS. This second draft PM Staff Paper is based on the information in the final PM AQCD, which had been the subject of review by the CASAC PM Panel, and builds upon the first draft PM Staff Paper (August 2003), which was the subject of review by the CASAC PM Panel in November 2003.

Preparation of this second draft PM Staff Paper benefitted substantially from the comments of the CASAC PM Panel on the first draft PM Staff Paper, as contained in a letter from former CASAC chair Dr. Hopke to the EPA Administrator (February 18, 2004). For example, taking the Panel's comments into consideration, we have more clearly distinguished between fine and thoracic coarse particles in discussions throughout this document, such as those related to air quality, exposure, and human health effects associations. Discussions of issues

related to the quantitative assessment of epidemiologic evidence have been revised reflecting the contents of the final PM AQCD as well as comments from the Panel. The human health risk assessment has been completed, with emphasis given to sensitivity analyses addressing the implications of the use of linear versus hypothetical non-linear concentration-response functions. Building upon comments from the Panel, we have conducted new analyses relating fine particles to visibility impairment, drawing from the extensive new air quality data available primarily for urban areas. Consistent with comments from the Panel, we have also moved the discussion of ecological effects toward a more risk-based framework, and have focused more on the concept of "critical loads."

Following completion of the OAQPS Staff Paper, the Agency will conduct a rulemaking with regard to its review of the PM NAAQS. Consistent with the terms of a consent decree, EPA will issue a notice of proposed rulemaking by December 20, 2005 and a final rulemaking notice by September 27, 2006.

Documents for Review

The following documents are available for review by the CASAC PM Panel in the form of attached electronic files or by downloading the documents from the EPA website http://www.epa.gov/ttn/naaqs/standards/pm/s_pm_cr_sp.html, except as noted below. Printed copies of these documents or a CD containing these electronic files are also available by contacting Dr. Mary Ross (ross.mary@epa.gov; 919-541-5170).

- **Attachment 1:** *Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information* (Second draft PM Staff Paper, January 2005)

  Following an introductory chapter (Chapter 1), this document is organized into three main topical areas:
  - characterization of ambient PM (Chapter 2);
  - PM-related health effects and primary NAAQS, including a policy-relevant assessment of PM health effects evidence (Chapter 3), quantitative assessment of human health risks (Chapter 4), and a review of the primary standards for fine and thoracic coarse particles (Chapter 5); and
  - PM-related welfare effects and secondary NAAQS, including a policy-relevant assessment of PM welfare effects evidence (Chapter 6) and a review of the secondary standards for fine and coarse fraction particles (Chapter 7).

  Provisional staff conclusions and recommendations for consideration in the review of the primary and secondary PM NAAQS are included in Chapters 5 and 7, respectively, recognizing that final staff conclusions and recommendations will be informed by comments from the CASAC PM Panel and the public on this document.

In this second draft Staff Paper, staff has broadened its approach to reaching conclusions and recommendations on the health-based primary PM standards. As discussed in Chapter 5, this approach places greater weight on epidemiologic evidence of associations between health effects and long-term exposures to fine particles and on the results from the quantitative risk assessment, especially for fine particles, in reaching conclusions and recommendations as to alternative averaging times, levels, and forms for consideration.

In summary, this second draft Staff Paper includes the following provisional staff recommendations for consideration in this review of the PM NAAQS:

- With regard to the primary $PM_{2.5}$ standards, consideration should be given to:
  - revising the suite of 24-hour and annual standards to provide increased public health protection;
  - revising the forms of the standards, to eliminate or more tightly constrain the use of spatial averaging with the annual standard, and to consider changing to a 99th percentile form or retaining the 98th percentile form for the 24-hour standard;
  - alternative suites of $PM_{2.5}$ standards, including an annual standard at the current level of 15 $\mu g/m^3$ together with a revised 24-hour standard in the range of 35 to 25 $\mu g/m^3$, or a revised annual standard in the range of 14 to 12 $\mu g/m^3$ together with a 24-hour standard in the range of 40 to 35 $\mu g/m^3$.

- With regard to the primary PM_{10} standards, the standards should be revised in part by changing the indicator to $PM_{10-2.5}$, and consideration should be given to:
  - retaining a 24-hour averaging time, and possibly an annual averaging time;
  - setting a 24-hour $PM_{10-2.5}$ standard with a level in the range of approximately 85 to 75 $\mu g/m^3$, with a 99th percentile form, or 75 to 65 $\mu g/m^3$, with a 98th percentile form; staff also notes some support for consideration of a range of levels down to about 35 to 30 $\mu g/m^3$.

- With regard to the secondary $PM_{2.5}$ and PM_{10} standards, consideration should be given to:
  - revising the current suite of $PM_{2.5}$ standards to provide increased and more targeted protection of visual air quality primarily in urban areas by setting a $PM_{2.5}$ standard with an averaging time of 4 to 8 daylight hours, in the range of about 30 to 20 $\mu g/m^3$, using a percentile-based form at or somewhat above the 90th percentile.
  - retaining standards for fine and coarse-fraction particles that at least retain the level of protection afforded by the current standards so as to continue control of ambient particles that contribute to adverse impacts on vegetation and ecosystems and materials damage and soiling.

The attached electronic file includes the entire draft Staff Paper and appendices except for a series of photographic images, discussed in Chapter 6 (Attachment 6A), showing visual air quality in several U.S. cities; these images are available online at the website identified above.

- **Attachment 2:** *Particulate Matter Health Risk Assessment for Selected Urban Areas: Second Draft Report* (Abt Associates, Inc., January 2005)

  The second draft Risk Assessment technical support document describes the methodology and presents the results from a PM health risk assessment for health risks associated with exposure to fine and thoracic coarse particles in a number of U.S. cities. The risk assessment methodology and results are summarized and discussed in Chapter 4 of the second draft Staff Paper. The attached electronic files contain the second draft Risk Assessment report and the extensive attachments to the report.

Listed below are several technical support documents prepared by OAQPS staff and cited in the second draft Staff Paper that are also being made available to the CASAC PM Panel to facilitate their review of the above documents.

- **Attachment 3:** *Draft Analyses of PM ambient air quality data for the PM NAAQS review* (Schmidt et al., 2005)

  This draft technical support memorandum provides comprehensive documentation of analysis methods, data sources, and results of the analyses of air quality and visibility data presented in the second draft Staff Paper; final documentation of these analyses will be completed in conjunction with preparation of the final Staff paper. This document is available online at http://www.epa.gov/oar/oaqps/pm25/, under the *Publications, Papers, Reports* section. Extensive supporting data files are available by request from Mr. Mark Schmidt (schmidt.mark@epa.gov; 919-541-2416).

- **Attachment 4:** *Updated statistical information on air quality data from epidemiologic studies* (Ross and Lanstaff, 2005)

  This technical support memorandum contains updated information on $PM_{2.5}$ and $PM_{10-2.5}$ air quality concentrations in a number of epidemiologic studies considered in this review.

- **Attachment 5:** *Estimation of Policy-Relevant Background Concentrations of Particulate Matter* (Langstaff, 2005)

  This technical support memorandum documents a staff analysis of policy-relevant background concentrations of PM.

- **Attachment 6:** *A Methodology for Incorporating Short-Term Variable Background Concentrations in Risk Assessments* (Langstaff, 2004)

  This technical support memorandum documents staff's approach to simulating distributions of daily $PM_{2.5}$ background concentrations used in a sensitivity analysis conducted as part of the $PM_{2.5}$ health risk assessment.

Charge to the CASAC PM Panel

Within each of the main sections of the second draft Staff Paper, questions that we ask the Panel to focus on in their review include the following:

PM air quality information and analyses (Chapter 2):

1. To what extent are the air quality characterizations and analyses clearly communicated, appropriately characterized, and relevant to the review of the primary and secondary PM NAAQS?

2. To what extent have appropriate distinctions been made between fine and coarse-fraction particles with regard to properties of ambient PM, spatial and temporal patterns of ambient PM, and relationships between ambient PM and human exposure?

3. Does the information in Chapter 2 provide a sufficient air quality-related basis for the human health and visibility assessments presented in later chapters?

PM-related health effects, risk assessment, and health-based standards (Chapters 3, 4, and 5):

1. To what extent is the presentation of evidence from the health studies assessed in the PM AQCD and the integration of information from across the various health-related research areas drawn from the PM AQCD technically sound, appropriately balanced, and clearly communicated?

2. What are the views of the Panel on the appropriateness of staff's discussion and conclusions in Chapter 3 on key issues related to quantitative interpretation of epidemiologic study results, including, for example, exposure error, the influence of alternative model specification, potential confounding or effect modification by co-pollutants, and lag structure?

3. What are the views of the Panel on the adequacy and clarity of staff discussions on the potential existence of thresholds in concentration-response relationships in Chapters 3, 4 and 5? In particular, to what extent are hypothetical thresholds addressed appropriately in the sensitivity analyses conducted as part of health risk assessment?

4. To what extent is the assessment, interpretation, and presentation of the results of the revised PM health risk assessment (as presented in Chapter 4 of the draft Staff Paper and in the draft Risk Assessment technical support document) technically sound, appropriately balanced, and clearly communicated?
   a. In general, is the set of health endpoints, epidemiologic studies, and concentration-response functions used in the assessment appropriate for both $PM_{2.5}$ and $PM_{10-2.5}$?
   b. In particular, what are the views of the Panel on the staff's approach of not including mortality associated with short-term exposure to $PM_{10-2.5}$ levels in the quantitative risk assessment given the overall weight of evidence for this effect?
   c. To what extent are the uncertainties associated with the risk assessment clearly and appropriately characterized in both the draft Staff Paper and draft Risk Assessment technical support document?
   d. What are the views of the Panel on the adequacy of the various sensitivity analyses conducted to evaluate the influence of uncertainties in the risk analyses?

5. What are the views of the Panel on the broader approach taken by staff (as discussed in Chapter 5) of using both evidence-based and quantitative risk-based considerations in reaching conclusions and recommendations as to alternative suites of standards to protect against health effects associated with long- and short-term exposures for consideration in this review of the PM NAAQS?
   a. Does the Panel generally agree with the emphasis given to the quantitative risk assessment results for $PM_{2.5}$, including consideration of risk estimates from base case and hypothetical threshold analyses, in reaching conclusions and recommendations for alternative suites of annual and 24-hour $PM_{2.5}$ standards?
   b. Does the Panel generally agree with placing less reliance on the $PM_{10-2.5}$ risk assessment results and giving more emphasis to the available evidence from health studies in reaching conclusions and recommendations for alternative $PM_{10-2.5}$ standards?

6. Does the Panel generally agree that the alternative suites of primary standards for fine particles (including indicator, averaging times, forms, and ranges of levels) recommended by staff are generally consistent with the available scientific information and are appropriate for consideration by the Administrator?

7. Does the Panel generally agree that the alternative standards for thoracic coarse particles (including indicator, averaging time(s), forms, and ranges of levels for a 24-hour standard) recommended by staff are generally consistent with the available scientific information and are appropriate for consideration by the Administrator?

PM-related welfare effects and welfare-based standards (Chapters 6 and 7):

1. To what extent is the presentation of evidence drawn from the PM AQCD related to the various welfare effects considered in this review technically sound, appropriately balanced, and clearly communicated?

2. To what extent is the characterization of the relationship between ambient PM and visibility impairment in urban areas scientifically sound and clearly communicated? In particular, what are the views of the Panel as to the methodology used to relate ambient $PM_{2.5}$ levels with reconstructed light extinction in urban areas across the U.S.?

3. Does the Panel generally agree that the local and state visibility standards and programs discussed in Chapter 6 are appropriate to help inform judgments as to the acceptability of varying levels of visibility impairment primarily in urban areas for the purpose of setting national standards?

4. Does the Panel generally agree that it is appropriate to consider using a fine particle mass indicator, specifically $PM_{2.5}$, as a basis for national standards intended to provide protection of visual air quality primarily in urban areas? Further, does the Panel generally agree that the alternative averaging times, forms, and range of levels recommended by staff for such standards are generally consistent with the available scientific information and are appropriate for consideration by the Administrator, in conjunction with the Regional Haze Program that is focused on protecting Class I areas from all man-made visibility impairment?

5. What are the views of the Panel as to the manner in which a risk-based framework has been used to organize the information presented in Chapter 6 on PM-related effects on vegetation and ecosystems?

6. What are the views of the Panel on the scientific soundness and usefulness of the discussion of the "critical loads" concept as a way to focus future research on the characterization, assessment, and protection of sensitive ecosystems?

We look forward to discussing these issues with the CASAC PM Panel at our upcoming meeting. Should you have any questions regarding the second draft PM Staff Paper, please contact me (martin.karen@epa.gov; 919-541-5274) or Dr. Mary Ross (ross.mary@epa.gov; 919-541-5170); questions about the risk assessment can be directed to Mr. Harvey Richmond (richmond.harvey@epa.gov; 919-541-5271).

Attachments

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John Bachmann, OAQPS/OD
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